K041158

MAY 24 2004

510(k) Summary
(As required by 21 CFR 807.92(a))

A. Submitter Information

Applied Diabetes Research, Inc.
1740 South IH 35E, Suite 112
Carrollton, TX 75006

Phone Number: 972-446-8406
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Contact: Rick Lynch
Regulatory Affairs
Date: April 29, 2004

B. Device Information

Trade/Proprietary Name:	THINSet 1.8 ml and 3.0 ml Reservoirs
Common name of device:	Infusion Pump Syringe
Classification Name:	Pump, Infusion

C: Predicate Device: THINSet 3.0 ml Reservoir

Predicate 510(k) #: K024056

D. Device Description:

The ThinSet Reservoir is a single use piston style syringe available with a capacity of 1.8 ml or 3.0 ml. It consists of a hollow barrel with a male Luer lock fitting at the distal end, removable rod and plunger with o-rings. This device is designed to deliver medications, including insulin, subcutaneously. The male Luer lock fitting of the reservoir is connected to the female Luer fitting of an infusion set. The reservoir is placed in an external infusion pump. The ThinSet Reservoir comes with a 22 gauge cannula.

E. Intended Use:

The THINSet 1.8 ml and 3.0 ml Reservoirs are indicated for use for the infusion of medicine, including insulin, from an external infusion pump. The reservoir is not indicated for use with blood or blood products.

K041152

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the THINSet 1.8 ml and 3.0 ml Reservoirs and the cited predicate device.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The intended use of the THINSet 1.8 ml and 3.0 ml Reservoirs is identical to that of the cited predicate device. Any differences in technological characteristics were insignificant and do not raise new issues of safety or effectiveness.

Performance testing consisted of the following:

Scale Accuracy

This test measures the accuracy of the dose markings on the syringe scale.

Plunger Exercise Test

This test was conducted per ISO 7886-1:1993(E) Annex G. This test measures the force to initiate plunger action as well as the maximum and minimum forces required to move the plunger within the Barrel.

Dose Accuracy Testing

Accuracy testing will be conducted similar to the requirements of ANSI/AAMI ID:26:1998, Particular requirements for the safety of infusion pumps and controllers. Instead of a motorized test figure, Infusion Pumps were used for the dose accuracy tests.

Conclusion:

The THINSet 1.8 ml and 3.0 ml Reservoirs are substantially equivalent to the THINSet 3.0 ml Reservoir in indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2004

Mr. Rick Lynch
Regulatory Affairs
Applied Diabetes Research, Incorporated
1740 South IH 35E, Suite 112
Carrollton, Texas 75006

Re K041152
Trade/Device Name: ThinSet 1.8 Ml and ThinSet 3.0 ml Reservoir
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: April 29, 2004
Received: May 3, 2004

Dear Mr. Lynch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041152

Indications for Use

510(k) Number (if known): K041152

Device Name: ThinSet 1.8 ml and ThinSet 3.0 ml Reservoir

Indications For Use:

The ThinSet Reservoir is indicated for use for the infusion of medicine, including insulin, from an insulin pump. The reservoir is not intended for use with blood or blood products.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Irene Nawaz for ADW
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041152